Significant Legislative Rule Analysis (SA)

WAC 246-310-010 and WAC 246-320-141 Certificate of Need and Hospitals October 1, 2013

Section 1. What is the scope of the rule?

Hospitals, licensed under chapter 70.41 RCW, are subject to Certificate of Need (CoN) under chapter 70.38 RCW. The Washington State Department of Health (department) is proposing to change the CoN process through rulemaking. The proposed changes in WAC 246-310-010 will clarify the term "corporation" as used in the existing definition of "person." A definition for "sale, purchase, or lease" of a hospital is also proposed. The proposed new definition will result in the requirement that when a hospital enters into an arrangement that effectively transfers "control" of the hospital from one person to another a CoN application must be submitted. This change improves transparency of significant hospital changes that have long lived impacts on the communities they serve.

The department is also proposing a new section of rules in WAC 246-320-141--Patient rights and organization ethics--that requires hospitals to submit their policies to the department on admission, non-discrimination, end of life care, and reproductive health care. Requiring hospitals to provide these policies improves transparency by the hospitals about consumer access to their services. This requirement will help consumers have access to important hospital information to help them make decisions on where to get their health care in advance of needing hospital services.

These proposed rules are in response to a directive from the Governor. Governor Jay Inslee issued Directive 13-12 on June 28, 2013, asking the department to review its CoN rules to consider "how the structure of affiliations, corporate restructuring, mergers and other arrangements among health care facilities results in outcomes similar to the traditional methods of sales, purchasing, and leasing of hospitals, particularly when control of part or all of an existing hospital changes from one party to another." The directive also said the rule process must "consider ways to improve transparency for consumer education and ease of use; specifically, the department shall ensure hospitals supply non-discrimination, end of life care, and reproductive health care policies," and that consumers have access to those policies.

Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?

RCW 70.38.015 establishes, "That strategic health planning efforts must be supported by appropriately tailored regulatory activities that can effectuate the goals and principles of the statewide health resources strategy developed pursuant to chapter 43.370 RCW. The implementation of the strategy can promote, maintain, and assure the health of all citizens in the state, provide accessible health services, health manpower, health facilities, and other resources

while controlling increases in costs, and recognize prevention as a high priority in health programs. Involvement in health planning from both consumers and providers throughout the state should be encouraged."

RCW 70.38.015 further establishes, "That the development and maintenance of adequate health care information, statistics and projections of need for health facilities and services is essential to effective health planning and resources development."

RCW 70.38.115 states that "Certificates of need shall be issued, denied, suspended, or revoked by the designee of the secretary in accord with the provisions of this chapter and rules of the department which establish review procedures and criteria for the certificate of need program."

Furthermore, RCW 70.38.135 states the Secretary of the Department of Health "shall have the authority to promulgate rules under which health care facilities providers doing business within the state shall submit to the department such data related to health and health care as the department finds necessary to the performance of its functions under the chapter."

Finally, RCW 70.41.030--Standards and Rules states "The department shall establish and adopt such minimum standards and rules pertaining to the construction, maintenance, and operation of hospitals, and rescind, amend, or modify such rules from time to time, as are necessary in the public interest, and particularly for the establishment and maintenance of standards of hospitalization required for the safe and adequate care and treatment of patients..."

Collectively, the statutes' objectives are to promote access to health care facilities in a planned and orderly manner through a public review process. The CoN rules are intended to help ensure that Washington residents have access to facilities and services by health care providers that are needed for quality patient care within a particular region or community. The proposed rules will:

- Consider how the structure of affiliations, corporate restructuring, mergers, and other arrangements among health care facilities result in outcomes similar to the traditional methods of sales, purchasing and leasing of hospitals, particularly when control of part or all of an existing hospital changes from one party to another;
- Improve transparency of hospital operations by ensuring that consumer have access to policies describing their services that will be posted on the department's web page and requiring similar posting on the hospital's web page.

Section 3. What is the justification for the proposed rule package?

The proposed rules will achieve the authorizing statutes' goals and objectives by ensuring that changes in hospital ownership or control are reviewed in a public process under CoN. Requiring hospitals to submit information on their access to care policies will improve transparency and assist the department in complying with the requirements of chapter 70.38 RCW.

The Department of Health has assessed and determined that there are no feasible alternatives to rulemaking. Rules are needed to require hospitals to submit the specified policies. Rules are also needed to clarify when a CoN application is necessary when hospitals enter into an arrangement that effectively transfers "control" of the hospital from one person to another person.

Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?

There are two significant rules that are proposed:

A. WAC 246-310-010—CoN Definitions (amended)

Rule Overview

The department is proposing to clarify the term "corporation" as used in the existing definition of "person." The amendment will clarify that corporations are either "public or private." This housekeeping change is non-significant. The department is also proposing adding a definition for what constitutes a "sale, purchase, or lease" of a hospital to include arrangements by contract, affiliation, corporate membership restructuring, or any other transaction in which the direct or indirect control of all or part of a hospital changes from one person (i.e., individual, trust, estate, corporation, state, political subdivision, or hospital district) to another.

The CoN program mandate is to promote access to cost effective health care services and facilities in a planned and orderly manner through a public review process. The CoN review for hospitals is initiated when there is a proposal to:

- Create a new hospital,
- Expand an existing hospital,
- Develop a new tertiary service in a hospital, and
- Sell, purchase, or lease of all or part of an existing hospital.

In general, as part of the CoN review, applicants must demonstrate that there is a need for their facility and include identifying services to be provided. The applicant must also demonstrate that the proposed project is financially feasible, that the staffing and quality of care (structure and process of care) is sufficient, and that there are no better options to meeting the community's identified need (cost containment). For hospital projects, changes in control through the current interpretation of sell, purchase, or lease, the review does not revisit the need of the facility. Instead the review is focused on impact to the community's residents on access to existing services, financial viability of the new controlling organization, and historical provision of quality care by the new controlling organization. The CoN review is a public process that is an extensive exercise for both the applicant to develop the required materials and the department's formal review of the applications. It also provides the community that is affected by the changes in the control of their local hospital the ability to participate in the review by having access to the application materials and providing the department input before a final CoN decision is made.

Since 2000, seven facilities completed a merger or affiliation through the restructuring of an existing or newly created organization. Under existing rules, these transactions were not

required to complete a CoN review. The department's position, however, is that these arrangements, in effect, have the same potential impacts to the residents of the community that sale, purchases, and leases have but without the assurances afforded by the public CoN review process these proposed rules put forward. This change of control through the restructuring of an existing or newly created organization justifies the need to conduct a new CoN review.

Rule Cost/Benefit Analysis

The department conducted a survey to estimate the compliance costs to hospitals. Most Washington State licensed hospitals were called. The purpose of this call was to contact key hospital leadership, explain the Governor's directive, explain the proposed Hospital Licensing rule changes, and to request feedback through completion of the hospital survey. The department was unable to personally reach key leadership of some hospitals, despite multiple calls to top level positions. The survey was emailed to 83 hospitals with a seven-day requested turn-around time. The department received 54 returned surveys.

Table 1 below presents the cost estimates to complete a CoN application provided by the responding hospitals.

Table 1. Survey Results for Cost to Complete a Certificate of Need Application

Hospital FTEs ¹	Potential to be an	Estimated cost to	Identify parts of estimated
	acquiring entity?	create a CoN application?	costs for CoN application?
66	No	n/a	n/a
85	No specific information provided	No specific information provided	No specific information provided
91	No	n/a	n/a
102	Unlikely	n/a	n/a
108	Confidential	n/a	n/a
135	No specific information provided	No specific information provided	No specific information provided
147	No	\$50,000	n/a
156	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
178	No	n/a	n/a
188	Yes	Very substantial	Do not know
196	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
199	No	\$40,000 plus	n/a
221	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc

¹ Hospital FTE information was obtained from department records.

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Hospital FTEs ¹	Potential to be an acquiring entity?	Estimated cost to create a CoN application?	Identify parts of estimated costs for CoN application?
228	Unlikely	\$50,000 to \$100,000	n/a
245	No	n/a	n/a
263	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
317	No	n/a	n/a
379	Prefer not to answer	\$70,000 to \$140,000	Consultants, legal, staff, misc
386	No	\$52,000	Staff, consultants, legal
443	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc
530	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting
546	No	n/a	n/a
563	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
576	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
698	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting
849	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics

Hospital FTEs ¹	Potential to be an acquiring entity?	Estimated cost to create a CoN application?	Identify parts of estimated costs for CoN application?
879	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
1,051	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
1,114	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc
1,157	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc
1,237	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
1,467	Yes	\$10,000 to \$50,000	Consultants, staff, legal
1,544	Yes	\$85,000 to \$125,000	Staff, medical, consultants, legal
1,700	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting
1,843	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
1,868	No specific information provided	No specific information provided	No specific information provided
1,917	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
2,041	Yes	\$10,000 to \$50,000	Consultants, staff, legal
2,262	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting

Hospital FTEs ¹	Potential to be an acquiring entity?	Estimated cost to create a CoN application?	Identify parts of estimated costs for CoN application?	
2,535	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc	
2,651	Yes	\$85,000 to \$125,000	Staff, medical, consultants, legal	
2,987	Yes	\$10,000 to \$50,000	Consultants, staff, legal	
3,212	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc	
3,299	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics	
3,633	Unknown	\$65,000 to \$70,000	Staff hours, physician hours, legal, consultants	
4,383	Yes	\$85,000 to \$125,000	Staff, medical, consultants, legal	
4,683	Yes	\$85,000 to \$125,000	Staff, medical, consultants, legal	
4,806	Unknown	Unable to estimate	n/a	
5,002	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc	
Not Available	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics	
Not Available	Yes	\$10,000 to \$50,000	Consultants, staff, legal	
Not Available	Yes	\$10,000 to \$50,000	Consultants, staff, legal	
Not Available	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc	
Not open	Not open Could occur in the Future \$45,000 to \$200,000		CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting	

Notes: 1. The above cost estimates do not include a \$40,700 CoN application fee.

The benefit of adding the definition of "sale, purchase, and lease" to include these other types of arrangements where the "control" of the hospital changes from one person to another is that it

^{2.} One hospital included \$380,000 estimated costs associated with legal actions. The department did not include this cost as part of the cost of compliance with the proposed rule.

provides Washington residents in communities impacted by these type of "control" changes the same public review and input process as those where the more traditional change in "control" have taken place. By establishing this definition, the department can promote access to health care services and facilities in a planned and orderly development manner; that patient care within a particular region or community is being met; and there is a public process to allow the communities impacted by the change in "control" for their community hospitals to have input to those decisions.

B. WAC 246-320-141--Patient rights and organizational ethics (amended)

Rule Overview

The department is proposing a rule amendment requiring hospitals to submit the following policies related to access of care: 1) admission, 2) non-discrimination, 3) end of life care, and 4) reproductive health care. Hospitals are already required to have admission, non-discrimination and end of life policies under other statutes and rules. The proposed rule will now require hospitals to have a reproductive health care policy. The department will post a copy of the policies it receives on its web site. In addition, if a hospital makes any changes to the policies, it must submit a copy of the changed policy to the department within 30 days of the approved change. Hospitals must submit the policies within 60 days of the effective date of the rule and also resubmit policies within 30 days if they make any changes or additions to the policy. Finally, hospitals must also post a copy of the policies to its own web site where it is readily accessible to the public, without requiring a login or any other restrictions to the public.

Rule Cost/Benefit Analysis

Hospitals licensed under chapter 70.41 RCW currently are required to have admission, non-discrimination, and end of life policies. These same hospitals may or may not have policies regarding reproductive health. The department also sought cost estimates from hospitals in the same survey process described in the previous section. Table 2 below presents survey results of the cost estimates of completing a reproductive health care policy and cost estimate to post the policy to each hospital's web site.

Table 2. Survey Results for Cost to Complete Proposed Policy Work

Hospital FTEs ²	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
66	No	\$1,000	80% legal, 20% staff	<\$20	\$500
85	No	\$2,325 to \$3,000	\$550 staff time, \$250 legal, copying \$25, staff training \$1,700		

² Hospital FTE information was obtained from department records.

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Hospital FTEs ²	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
91	No	\$5,000 to \$10,000	20% staff, 80% legal	<\$100	<\$100
102	No	Uncertain	No specific information provided	Minimal	Minimal
108	No	No specific information provided	n/a	Nominal	\$3,050
135	No	No specific information provided	No specific information provided	No specific information provided	No specific information provided
147	No	\$500 to \$1000	Legal, staff	\$25	Minimal
156	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
178	No	\$700 to \$1,200	\$900 staff hours, \$300 legal	\$10	\$150
188	No	Unable to estimate	Unable to estimate	<\$100	Not exorbitant
196	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
199	No	\$1,890	\$800 legal, \$1090 staff	Minimal	Minimal
221	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors,	\$107.76	\$520 to \$780

Hospital FTEs ²	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
			Archbishop, implementation, communications		
228	No	\$1,500	\$1,000 staff, \$500 legal	Depends on how they are sent?	Minimal
245	No	\$100 to \$400	Staff, legal	Copying costs \$5, staff time \$31, Postal rate \$9	\$50
263	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
317	No	\$20,000 to \$25,000	20% staff time, 80% legal expense	Minimal	Minimal
379	No	\$5,000 to \$10,000	Staff, legal, misc	\$5 to \$10	\$50 to \$100
386	No	\$5,350	Staff hours, legal hours	\$100	\$260
443	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488
530	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100
546	No	\$10,500	\$4,500 legal, \$2,000 physician, \$4,000 staff	\$10	\$200 to \$400
563	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000

Hospital FTEs ²	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
576	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
698	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100
849	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
879	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
1,051	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
1,114	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488

Hospital FTEs ²	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
1,157	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488
1,237	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
1,467	No	No specific information provided	n/a	Minimal	Minimal
1,544	No	\$70,000 to \$100,000	Medical, administrative, staff, governing bodies, legal	Cost of admin prep time and postage	Cost of admin time which is unknown?
1,700	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100
1,843	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
1,868	No specific information provided	No specific information provided	No specific information provided	No specific information provided	No specific information provided
1,917	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000

Hospital FTEs ²	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
2,041	No	No specific information provided	n/a	Minimal	Minimal
2,262	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100
2,535	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
2,651	No	\$70,000 to \$100,000	Medical, administrative, staff, governing bodies, legal	Cost of admin prep time and postage	Cost of admin time which is unknown?
2,987	No	No specific information provided	n/a	Minimal	Minimal
3,212	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
3,299	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
3,633	Uncertain	\$16,000 to \$20,000	Staff hours, physician hours, legal	\$50	\$2,500

Hospital FTEs ²	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
4,383	No	\$70,000 to \$100,000	Medical, administrative, staff, governing bodies, legal	Cost of admin prep time and postage	Cost of admin time which is unknown?
4,683	No	\$70,000 to \$100,000	Medical, administrative, staff, governing bodies, legal	Cost of admin prep time and postage	Cost of admin time which is unknown?
4,806	No	\$5,000	Legal, regulatory, compliance, clinic operations	Very low	Uncertain
5,002	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488
Not Available	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
Not Available	No	No specific information provided	n/a	Minimal	Minimal
Not Available	No	No specific information provided	n/a	Minimal	Minimal
Not Available	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488
Not open	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100

The benefit of requiring hospitals to submit these policies is to increase transparency of consumer information.

Rule Package Cost-Benefit Conclusion

The proposed rules will have a financial impact on those hospitals that have to complete a CoN review for an arrangement, other than a traditional sale, purchase, or lease where the control of the hospital is changed from one person to another. There will be a financial impact for hospitals to develop a policy on reproductive health care, to send copies of the four policies to the department, and to post policies their web site. The benefits are: ensuring that there is a public process for reviewing changes in hospital ownership or control under CoN and increasing transparency of hospital operations regarding access to care. Therefore, the total probable benefits of the rule exceed the total probable costs.

Section 5. What alternative versions of the rule were considered? Is the proposed rule the least burdensome approach?

The department circulated draft rules requiring hospitals to submit a list of services that was limited or not available because of the access to care policies. Concerns were raised by some stakeholders that the term "reproductive health care" was vague, and does not describe what the department is looking for in terms of specific services. The department decided to strike from the draft rules the requirement of a list of services that are limited or not available.

The purpose of these rules is not to specify what is required in a reproductive health policy but simply to require hospitals to submit policies that reflect current practices and make that information available and transparent to the public. The department determined the least burdensome approach to achieving the goals and objectives of the proposed rule would be to publish the submitted hospital policies on reproductive health services, admission, non-discrimination, and end of life care on the department's web site.

Section 6. Does the rule require anyone to take an action that violates another federal or state law?

The department has determined that the proposed rules do not require those to whom it would apply to take an action that violates requirements of federal or state law.

Section 7. Does the rule impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?

The department has determined that the proposed rules do not impose more stringent performance requirements on private entities than on public entities.

Section 8. Does the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, is this difference justified by an explicit state statute or by substantial evidence that the difference is necessary?

The proposed rules do not differ from any applicable federal regulation or statute.

Section 9. Has the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?

There are no other applicable laws.